

UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF WASHINGTON  
AT SEATTLE

YVONNE A'RAE LAISURE-RADKE,  
*et al.*,

Plaintiffs,

v.

PAR PHARMACEUTICAL, INC., *et al.*,

Defendants.

CASE NO. C03-3654RSM

ORDER DENYING MOTION TO EXCLUDE  
TESTIMONY OF GEORGE S. GLASS, M.D.,  
P.A., AND JOSEPH GLENMULLEN, M.D.

**I. INTRODUCTION**

This matter comes before the Court on defendants' Motion to Exclude the Testimony of George S. Glass, M.D., P.A., and Joseph Glenmullen, M.D. (Dkt. #116). Defendants ask this Court to bar plaintiffs from utilizing during the course of trial or offering into evidence the testimony of Drs. Glass and Glenmullen on the basis that their testimony and opinions are not based on a reliable foundation, and because they lack the requisite qualifications to render such opinions.

Plaintiff opposes the motion, asserting that her experts are well qualified by their knowledge, skill, experience, training and education, to render opinions in this case. (Dkt. #130, Attachment 21).

For the reasons set forth below, the Court agrees with plaintiff and DENIES defendants' motion to exclude.

## **II. DISCUSSION**

### **A. Background**

Plaintiff, Yvonne A'Rae Laisure-Radke, brings this lawsuit on behalf of herself and as individual representative of her husband's estate. She alleges that her husband, Douglas Radke, committed suicide while under the influence of the antidepressant drug fluoxetine, which is the generic version of Eli Lilly's Prozac. Defendants manufacture, distribute and market the generic drug. Plaintiff essentially asserts that defendants were aware of an increased risk of suicidality in users of the class of antidepressant drugs within which Fluoxetine lies, known as selective serotonin reuptake inhibitors ("SSRIs"), well before the death of Ms. Laisure-Radke's husband, and did not adequately warn of that risk.

Plaintiff has designated two expert witnesses, Dr. Glass and Dr. Glenmullen. Both are expected to testify as to the association between fluoxetine and akathisia, and the association between akathisia and suicidality.<sup>1</sup> It appears that Dr. Glenmullen will provide opinions on both general and specific causation, and Dr. Glass will provide opinions on specific causation.

Defendants argue that neither Dr. Glass nor Dr. Glenmullen are qualified to render these opinions, and, in any event, their opinions are not based on generally accepted methodology. Thus, defendants ask this Court to exclude both doctors as expert witnesses.

### **B. Expert Testimony**

Federal Rule of Evidence 702 provides:

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts

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<sup>1</sup> Akathisia is a condition described as inner feelings of restlessness along with physical symptoms of agitation. Some experts have testified that people view death as a welcome result when akathisia is present with other mood disorders.

1 or data, (2) the testimony is the product of reliable principles and methods, and (3)  
2 the witness has applied the principles and methods reliably to the facts of the case.

3 Fed. R. Evid. 702. In *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993), the United States  
4 Supreme Court explained that in considering the admission of expert scientific testimony in a federal  
5 trial, “the trial judge must ensure that any and all scientific testimony or evidence admitted is not only  
6 relevant, but reliable.” *Daubert*, 509 U.S. at 589. The court went on to instruct that the trial court  
7 should first look to Rule 702, which mandates that an expert’s testimony must be “scientific knowledge  
8 . . . derived by the scientific method . . . [and] supported by appropriate validation.” *Id.* at 589-90.

9 As guidance, the Supreme Court discussed four factors it deemed relevant to the determination  
10 of whether certain expert testimony should be admitted:

11 Ordinarily, a key question to be answered in determining whether a theory or  
12 technique is scientific knowledge that will assist the trier of fact will be whether it can  
13 be (and has been) tested. . . . Another pertinent consideration is whether the theory  
14 or technique has been subjected to peer review and publication. . . . Additionally, in  
15 the case of a particular scientific technique, the court ordinarily should consider the  
16 known or potential rate of error, and the existence and maintenance of standards  
17 controlling the technique’s operation. . . . Finally, ‘general acceptance’ can yet have  
18 a bearing on the inquiry. A ‘reliability assessment does not require, although it does  
19 permit, explicit identification of a relevant scientific community and an express  
20 determination of a particular degree of acceptance within that community.’  
21 Widespread acceptance can be an important factor in ruling particular evidence  
22 admissible, and ‘a known technique which has been able to attract only minimal  
23 support within the community,’ may properly be viewed with skepticism.  
24 . . .

25 The inquiry envisioned by Rule 702 is, we emphasize, a flexible one. Its overarching  
26 subject is the scientific validity -- and thus the evidentiary relevance and reliability --  
of the principles that underlie a proposed submission. The focus, of course, must be  
solely on principles and methodology, not on the conclusions that they generate.

*Daubert*, 509 U.S. at 595 (citations omitted).

Furthermore, the *Daubert* court instructed district judges to be aware of other evidentiary rules  
in assessing expert testimony. For example, Rule 703 allows experts to rely upon facts or data that  
aren’t admissible into evidence when forming their opinions or inferences, so long as the facts or data  
are of a type reasonably relied on by experts in the particular field. Fed. R. Evid. 703.

1 In the instant case, defendants first examine the qualifications of the proffered doctors.  
2 Defendants note that Dr. Glenmullen has never participated in, designed, or written the protocol for a  
3 controlled clinical trial or any scientific study of either a psychoactive or any other drug; he has never  
4 served as the principal investigator for any scientific study and has never administered any psychiatric or  
5 psychological rating scales or testing instruments in any clinical study; he has never participated in,  
6 designed or written a protocol for any epidemiological or large group study of a psychoactive drug or  
7 of any drug; he has not performed clinical or laboratory research regarding potential side effects  
8 associated with any SSRI antidepressant, including fluoxetine; he has never published a peer-reviewed  
9 article or other writing on SSRI antidepressants, antidepressants in general, suicidality or any aspect of  
10 medicine; he has never written or published a paper, study, or article in any scientific or medical journal  
11 on any subject; he has never served as a peer-reviewer for any medical or scientific journal; he does not  
12 belong to any professional organization which focuses on the study of psychoactive drugs or any other  
13 relevant professional organization; and he is not a researcher or scientist. Defendants argue that these  
14 deficiencies preclude Dr. Glenmullen from testifying as an expert in this case.

15 Plaintiff responds that Dr. Glenmullen's extensive real life experience in treating patients, his  
16 Board Certification in Psychiatry and Neurology, his forensic training and academic appointments,  
17 provide the requisite qualifications. Plaintiff notes that Dr. Glenmullen is a Harvard-trained psychiatrist  
18 who has practiced psychopharmacology and psychiatry at Harvard University for more than two  
19 decades, he has prescribed SSRIs, seen the side affects about which he testifies, and has treated those  
20 side affects. Dr. Glenmullen has also written books examining Prozac-induced suicide. Plaintiff also  
21 notes that defendants have continuously criticized Dr. Glenmullen since he wrote and published his  
22 book "Prozac Backlash."

23 The Court finds plaintiff persuasive. There is no question that experience-based expert  
24 testimony is admissible. Indeed the Ninth Circuit Court of Appeals has held that any allegations of lack  
25 of particularized expertise, such as those raised by defendants above, goes to the weight accorded to

1 the testimony, not its admissibility. *United States v. Garcia*, 7 F. 3d 885, 890 (9th Cir. 1993).

2 Therefore, the Court does not agree with defendants that Dr. Glenmullen is not properly qualified to  
3 testify as an expert witness in this case.

4 Similarly, the Court finds that Dr. Glass is also qualified to testify as an expert in this case.  
5 While defendants raise essentially the same deficiencies in qualifications as those raised against Dr.  
6 Glenmullen, the Court notes that Dr. Glass has more than 30 years of experience treating patients, he  
7 has board certifications in both Psychiatry and Addictionology, he is a Yale-educated physician and  
8 psychiatrist, and he has prescribed SSRIs, seen the side affects about which he testifies, and has treated  
9 those side affects.

10 However, while the Court agrees that both doctors may be qualified to testify as expert  
11 witnesses, the U.S. Supreme Court has directed that such experience-based testimony is still subject to  
12 the *Daubert* test for reliability. *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 141 (1999). Thus, the  
13 Court now turns to such an analysis.

14 In *Kumho Tire Co.*, the Supreme Court provided district courts with guidance as to what to  
15 consider when determining the reliability of an expert witness's testimony, emphasizing that such an  
16 analysis is a flexible one:

17 The petitioners ask more specifically whether a trial judge determining the  
18 'admissibility of an engineering expert's testimony' may consider several more  
19 specific factors that *Daubert* said might 'bear on' a judge's gate-keeping  
20 determination. These factors include:

21 -- Whether a 'theory or technique . . . can be (and has been) tested;

22 -- Whether it 'has been subjected to peer review and publication';

23 -- Whether, in respect to a particular technique, there is a high 'known  
24 or potential rate of error' and whether there are 'standards controlling  
25 the technique's operation'; and

26 -- Whether the theory or technique enjoys 'general acceptance' within a  
'relevant scientific community.'

Emphasizing the word 'may' in the question, we answer that question yes.

1 Engineering testimony rests upon scientific foundations, the reliability of which will  
2 be at issue in some cases. In other cases, the relevant reliability concerns may focus  
3 upon personal knowledge or experience. As the Solicitor General points out, there  
4 are many different kinds of experts, and many different kinds of expertise. Our  
5 emphasis on the word ‘may’ thus reflects *Daubert*’s description of the Rule 702  
6 inquiry as ‘a flexible one.’ *Daubert* makes clear that the factors it mentions do not  
7 constitute a ‘definitive checklist or test.’ And *Daubert* adds that the gatekeeping  
8 inquiry must be “‘tied to the facts’” of a particular ‘case.’ We agree with the  
9 Solicitor General that ‘the factors identified in *Daubert* may or may not be pertinent  
10 in assessing reliability, depending on the nature of the issue, the expert’s particular  
11 expertise, and the subject of his testimony.’ The conclusion, in our view, is that we  
12 can neither rule out, nor rule in, for all cases and for all time the applicability of the  
13 factors mentioned in *Daubert*, nor can we now do so for subsets of cases categorized  
14 by category of expert or by kind of evidence. Too much depends upon the particular  
15 circumstances of the particular case at issue. *Daubert* itself is not to the contrary.  
16 It made clear that its list of factors was meant to be helpful, not definitive. Indeed,  
17 those factors do not all necessarily apply even in every instance in which the reliability  
18 of scientific testimony is challenged. It might not be surprising in a particular case,  
19 for example, that a claim made by a scientific witness has never been the subject of  
20 peer review, for the particular application at issue may never previously have  
21 interested any scientist. Nor, on the other hand, does the presence of *Daubert*’s  
22 general acceptance factor help show that an expert’s testimony is reliable where the  
23 discipline itself lacks reliability, as, for example, do theories grounded in any so-called  
24 generally accepted principles of astrology or necromancy.

25 *Kumho Tire Co.*, 526 U.S. at 151 (citations omitted).

26 In the instant case, as noted above, Dr. Glenmullen is a psychiatrist who has treated depressed  
patients for more than 20 years and has prescribed fluoxetine and other antidepressants on a regular  
basis. Based on numerous published case reports, peer-reviewed articles and studies, his own research  
for his two books “Prozac Backlash” and “The Antidepressant Solution,” and his own observations of  
the case materials, Dr. Glenmullen intends to testify that Douglas Radke’s death was fluoxetine-induced  
suicide. He also intends to testify as to the general causation between SSRIs and suicide by focusing on  
the relationship between fluoxetine and akathisia, and the relationship between akathisia and suicidality.

Defendants challenge Dr. Glenmullen’s method of “connecting the dots” between the  
intermediary step of akathisia and suicidality, and argue that this is not a generally accepted  
methodology to assess an alleged causal relationship between fluoxetine and suicide. The Court  
disagrees.

1 While the Court recognizes that Dr. Glenmullen's opinions are not based on his own peer  
2 reviewed publications or studies that he conducted himself, the Court acknowledges that his findings  
3 are based on his extensive experience as a clinician prescribing antidepressants, including fluoxetine,  
4 and his extensive review of the materials, reports, and other relevant materials of this case. *See*  
5 *generally, McKendall v. Crown Control Corp.*, 122 F.3d 803 (9th Cir. 1997) (admitting, without  
6 applying the *Daubert* standard, expert testimony of an engineer who had over thirty years of experience  
7 and extensive expertise). In addition, Dr. Glenmullen's opinion is supported by the Jick study<sup>2</sup> and  
8 numerous other medical articles to which he cites in his expert report that suggest a causal connection  
9 between fluoxetine and suicide. Accordingly, the Court finds that Dr. Glenmullen's opinions are  
10 adequately supported by scientific theory and factual bases.

11 Likewise, the Court also finds that Dr. Glenmullen's proposed testimony would aid the trier of  
12 fact in this case. Dr. Glenmullen's experience as a psychiatrist, along with the fact that he has  
13 prescribed fluoxetine and treated the side effects, demonstrates his knowledge about SSRIs and their  
14 effects on patients in a real world setting. Similarly, as highlighted above, his review of the Jick study  
15 and numerous other medical journals supports his causation theory. As such, his proposed testimony  
16 will assist the jury in forming its own decisions pertaining to causation and liability. Accordingly, the  
17 Court finds Dr. Glenmullen's testimony admissible under *Daubert*. For the same reasons, the Court  
18 finds that Dr. Glass's testimony is also admissible under *Daubert*. Thus, the Court declines to exclude  
19 either doctor as an expert witness in this case.

20 This is not to say that defendants are without other recourse for challenging the expert  
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22 <sup>2</sup> Jick, S., *Antidepressants and Suicide*, Br. Med. J. 1995; 310:215-18. The Jick study  
23 followed 172,598 people who had been taking at least one of ten antidepressants, and determined  
24 which of them committed suicide. One of the ten drugs was fluoxetine. The results showed that 143  
25 of the subjects committed suicide. The researchers analyzed the data for each drug in different  
26 respects such as effect of suicidal history and use of antidepressants, effect of time from first  
prescription to suicide, and effect of depressive illness. They also compared each drug with Dothiepin  
(the most commonly used antidepressant) as an arbitrary reference point for statistical analysis.

1 testimony at issue in this motion. The Court reminds defendants that plaintiff's expert testimony  
2 remains subject to the traditional "safeguards" present in all litigated cases. *Daubert*, 509 U.S. at 596.  
3 As the Supreme Court explained:

4 [v]igorous cross-examination, presentation of contrary evidence, and careful  
5 instruction on the burden of proof are the traditional and appropriate means of  
6 attacking shaky but admissible evidence. Additionally, in the event the trial court  
7 concludes that the scintilla of evidence presented supporting a position is insufficient  
8 to allow a reasonable juror to conclude that the position more likely than not is true,  
9 the court remains free to direct a judgment, and likewise to grant summary judgment.  
10 These conventional devices . . . are the appropriate safeguards where the basis of  
11 scientific testimony meets the standards of Rule 702.

12 *Id.* (citations omitted).

### 13 III. CONCLUSION

14 Having reviewed defendants' motion, plaintiff's response, defendants' reply, the numerous  
15 exhibits and declarations in support of those briefs, and the remainder of the record, the Court hereby  
16 finds and ORDERS:

17 (1) Defendants' Motion to Exclude the Testimony of Drs. Glenmullen and Glass (Dkt. #116) is  
18 DENIED.

19 (2) The Clerk shall forward a copy of this Order to all counsel of record.

20 DATED this \_\_\_\_ day of March 2006.

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22 RICARDO S. MARTINEZ  
23 UNITED STATES DISTRICT JUDGE  
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